UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

JONATHAN A. BLOOM, Plaintiff, v. ERIC D. HARGAN, Acting Secretary , U.S. Department of Health and Human Services, Defendant.	)))))))))	Civil No. 5:16-cv-121

DEFENDANT'S RESPONSE TO
PLAINTIFF'S NOTICE OF SUPPLEMENTAL AUTHORITY

Defendant Eric D. Hargan, Acting Secretary of the United States Department of Health and Human Services ("the Secretary") respectfully submits the following response to Plaintiff's Notice of Supplemental Authority.

Defendant acknowledges the recent decision of the Eastern District of Wisconsin in *Whitcomb v. Hargan*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) ("Decision"), which involves the request of a Medicare Advantage plan member for coverage of a Medtronic MiniMed continuous glucose monitoring ("CGM") system. In its October 26, 2017 decision, the *Whitcomb* court ruled that the Medicare Appeals Council erred in denying coverage for the plaintiff's CGM system because the plaintiff's CGM is "primarily and customarily used to serve a medical purpose." Decision at 13 (citing 42 C.F.R. § 414.202). In particular, the court found that the plaintiff's CGM "does not serve a non-medical purpose," and that the Secretary's interpretation of his regulation to "require equipment to serve a primary medical purpose" was unreasonable. *Id.* at 11, 13. The Secretary respectfully disagrees with the reasoning (and conclusions) articulated in the *Whitcomb* decision, which is not binding on this Court, and further

contends that the underlying facts in *Whitcomb* are distinguishable from the coverage dispute at issue in the instant case.

The Secretary disagrees with the court's analysis of the "primarily and customarily used to serve a medical purpose" criterion. As an initial matter, while Plaintiff's CGM device may be within a realm of medical devices generally, that does not (and should not) automatically mean the device is "primarily and customarily used to serve a medical purpose" as required for Medicare eligibility. For the *Whitcomb* court, simply because a CGM "does not serve a non-medical purpose," the device is primarily and customarily engaged in serving a medical purpose. Decision at 11-12. However, such an expansive reading of this portion of the DME regulation is unreasonable, as it opens the door for coverage of medical devices that may not be safe and effective for a beneficiary's use. The *Whitcomb* court's reading is further contrary to NCD 280.1, which indicates that DME coverage decisions for items not listed in that document must take into account "[w]hether the item has been approved for marketing by the Food and Drug Administration (FDA) and is otherwise generally considered to be safe and effective for the purpose intended." *Medicare National Coverage Determinations Manual*, CMS Pub. No. 100-03, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html.

In this case, Plaintiff has indicated that he uses his CGM system for the medical purpose of controlling his diabetes. *See, e.g.*, Compl. ¶ 86 ("Dr. Bloom's healthcare provider attested that CGM was and is reasonable and medically necessary for Dr. Bloom to control his diabetes."); Pl.'s Br. at 14-15 (describing the CGM as "the primary means by which [brittle diabetics] control their diabetes."). The proper inquiry, then, is whether the CGM is primarily and customarily used to serve that medical purpose. As the *Whitcomb* court acknowledged, the CGM system in

that case (which appears to be the same CGM at issue here) is "secondary" in serving such a medical purpose. *See* Decision at 12, 14. Plaintiff has made the same showing here: that is, that his CGM system is neither primarily nor customarily used to control his diabetes. Indeed, Plaintiff has admitted that his CGM system cannot take the place of traditional blood glucose monitoring, and that its interstitial glucose readings must be confirmed by traditional blood glucose monitoring. *See* Administrative Record ("A.R.") M-15-4332, at 385. Once Plaintiff has conducted a traditional blood glucose reading, he may then safely and accurately make a treatment decision to control his disease, but not before. *Id*.[1] Consequently, Plaintiff's traditional blood glucose meter is the device primarily and customarily used by him for the medical purpose of controlling his diabetes, not his CGM system.

As a final matter, unlike the *Whitcomb* case, the Secretary has neither conceded nor determined that Plaintiff has demonstrated the remaining criteria required for Medicare coverage—specifically, that Plaintiff's CGM system and supplies are reasonable and necessary.[2] *Compare* Decision at 15. The Secretary, in the first instance, must decide this issue. Thus, even if this Court were to find that Plaintiff's CGM satisfied the regulatory criteria for DME, a remand for a determination of whether Plaintiff's CGM system and supplies are reasonable and necessary would be the appropriate course of action, not reversal and remand for payment of the

[1] As described in the Secretary's motion, the medical literature submitted by Plaintiff during the administrative proceedings in M-16-10554 similarly indicated that a CGM is not primarily and customarily used for the medical purpose of controlling an individual's diabetes. *See, e.g.,* A.R. M-16-10554, at 472, 496, 500-501, 504, 523.
[2] In the underlying ALJ decisions at issue in M-15-4332, which the Secretary has argued is the only final decision properly before the Court, the ALJs did not reach the question of whether Plaintiff's CGM was reasonable and necessary. *See* A.R. M-15-4332, at 4-5.

claims.

Dated at Burlington, in the District of Vermont, this 9th day of November, 2017.

Respectfully Submitted,

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Acting United States Attorney

By: /s/ *Melissa A. D. Ranaldo*

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